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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,817	06/08/2001	Austin Gerard Smith	06999.0010-0	6701

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EXAMINER

WILSON, MICHAEL C

ART UNIT PAPER NUMBER

1632

DATE MAILED: 05/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/786,817

Applicant(s)
Smith et al.

Examiner
Michael C. Wilson

Art Unit
1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 13, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 14-21, 25-28, 30-39, 43, 44, and 46-50 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 12, 14-21, 25-28, 30-39, 43, 44, and 46-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Upon reconsideration, a clarification of the restriction requirement is necessary. Claims 12, 14-21, 25-28, 30-39, 43, 44 and 46-50 remain pending and under consideration.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 12, 14-21, 25-28, 30-39, 43, 44 and 50, drawn to a composition comprising a) a compound that promotes propagation of ES cells and b) a compound that inhibits activity of SHP-2, culture medium comprising the composition, and a method of culturing ES cells with said composition, and a method of culturing ES cells with a compound that inhibits activity of SHP-2.

Group II, claims 12, 14-21, 25-28, 30-39, 43, 44 and 46-50, drawn to a composition comprising a) a compound that promotes propagation of ES cells and b) a compound that inhibits MEK, culture medium comprising the composition, a method of culturing ES cells with said composition, a method of culturing ES cells with a compound that inhibits MEK.

Group III, claims 12, 14-21, 25-28, 30-39, 43, 44 and 50, drawn to a composition comprising a) a compound that promotes propagation of ES cells and b) a compound that inhibits

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a mitogen activated protein kinase (MAPK), culture medium comprising the composition, a method of culturing ES cells with said composition, a method of culturing ES cells with a compound that inhibits a mitogen activated protein kinase.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the claims encompass culturing cells isolated from a blastocyst transfected with a vector encoding a selectable marker operably linked to the oct-4 promoter (US Patent 6,146,888). The vector is a compound that both promotes propagation of the ES cells and inhibits propagation of non-ES cells.

Claims 46-49, directed toward a ^{second} ~~first~~ compound that is PD098059 are specific to “inhibitors of MEK” as taught in the specification (pg 5, line 27). The limitations of “compounds that inhibit the ras/MAPK cascade” and “that inhibit cyclin dependent entry into S-phase of non-ES cells” share an undisclosed overlap with the species above. For example, an inhibitor of MEK such as PD098059 (pg 5, line 27) is also an inhibitor of the ras/MAPK cascade because MEK is part of the ras/MAPK cascade (see references provided in the response filed 2-13-03). The basis of the restriction is the first compound which must inhibit the function of a specific protein. Inhibiting the ras/MAPK cascade or inhibiting the entry of non-ES into S-phase is the result of inhibiting a specific protein. It cannot be determined what proteins must be inhibited to “inhibit non-ES cells entry into S-phase” as claimed. While it is clear that inhibitors

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of MEK and MAPK as claimed are species of the genus "compounds that inhibit the ras/MAPK cascade," it cannot be determined whether inhibiting SHP-2 inhibits the ras/MAPK cascade.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The following 3 compounds are generic to numerous species:

a compound that inhibits activity of SHP-2,

a compound that inhibits MEK, and

a compound that inhibits a mitogen activated protein kinase.

If applicants elect group I, applicant is required, in reply to this action, to elect a single species of "a compound that inhibits activity of SHP-2" disclosed in the specification to which the claims shall be restricted if no generic claim is finally held to be allowable.

If applicants elect group II, applicant is required, in reply to this action, to elect a single species of "a compound that inhibits MEK" disclosed in the specification to which the claims shall be restricted if no generic claim is finally held to be allowable.

If applicants elect group III, applicant is required, in reply to this action, to elect a single species of "a compound that inhibits a mitogen activated protein kinase" disclosed in the specification to which the claims shall be restricted if no generic claim is finally held to be allowable.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

2. The claims are deemed to correspond to the species listed above in the following manner:

Claims 12, 14-21, 25-28, 30-39, 43, 44 and 50 are generic to any of the species.

Claims 46-49 are specific to PD098059 which is an inhibitor of MEK (pg 5, line 27).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the inhibitors of SHP-2, MEK and MEK have different modes of action, different structures, and act of different proteins. A compound that inhibits the function of SHP-2 would not inhibit the function of MEK or MEK. A compound that inhibits the function of MEK would not inhibit the function of SHP-2 or MEK. A

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compound that inhibits the function of MEPK would not inhibit the function of MEK or SHP-2.

Therefore, the inventions do not share the same "special technical feature."

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson



**MICHAEL WILSON
PRIMARY EXAMINER**